

therapy, with a lower risk of hypoglycemia and without affecting weight versus sulfonylurea and metformin combination.

#### PDB24

##### RECOMBINANT GROWTH HORMONE THERAPY IN CHILDREN WITH GH DEFICIENCY: FIRST INTERVENTIONAL STUDY IN ARMENIA

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**OBJECTIVES:** The purpose of this study was to evaluate the effectiveness and safety of treatment with recombinant growth hormone (RGH) in children with GH deficiency. **METHODS:** This was an interventional study with 6 and 12 months follow-up. Treatment was received by 15 children. The patients were receiving the RGH in 0.033 mg/kg (0.1 Unit/kg) at the same time each day (9–10 pm) for period of 1 year. The effectiveness of treatment was evaluated based on change in growing speed, growth SDS and bone age maturation. **RESULTS:** The mean age of children was 9.5±3.6 years. In the given sample 6 children had MHPD, other 9 children had IGHD. There was a great improvement in absolute growth at 6 and 12 months period of treatment (p<0.001; p<0.001). The same was found for growth SDS (p<0.001; p<0.001). Effectiveness of RGH therapy on bone age maturation also showed great improvement (p<0.001; p<0.001). The level of IGF-1 was increased (p<0.001; p<0.001); at 12 months the level of IGF-1 reached to 248.72±70.7 ng/mL and remained consistently high. The same improvement was in IGF-pb3 levels (p<0.001; p<0.001). The lipidemic analysis showed that the blood cholesterol levels were from 3.21 to 12.39 mmol/L (norm 5.68±1.55 mmol/L) and the level of LDL - 1.3 to 10.86 mmol/L (norm 3.83±1.44 mmol/L). During the treatment period we observed the significant improvement in cholesterol levels (p<0.001; p<0.001). High density lipoprotein and triglyceride levels did not change significantly (p. 0.05). **CONCLUSIONS:** It can be concluded that the treatment with RGH in patient with GH deficiency is beneficial as it normalized the levels of cholesterol and LDL. During the treatment there were no any changes in indicators of kidney's function, indicators of liver's function as well as the indicators of carbohydrate metabolism.

#### PDB25

##### EFFECTIVENESS, SAFETY AND PATIENTS' SUBJECTIVE FEELINGS OF INSULIN PEN-NEEDLE: A SYSTEMATIC REVIEW

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**OBJECTIVES:** To compare the differences of effectiveness, safety and patients' subjective feelings for using different lengths of insulin pen-needle in diabetic patients. **METHODS:** A retrospective analysis of relevant publications that were identified via electronic searches of databases using multiple search terms related to insulin pen-needle. **RESULTS:** Totally, 21 literatures were included. Firstly, for the effectiveness, 85.71% of the studies suggested that there was no difference between longer and shorter needle in controlling HbA1c, 14.29% thought the shorter needle was better than the longer. No changes were observed with respect to fructosamine, glycated albumin and body mass index. Secondly, about the safety, all of the studies proved that the shorter needle was better in intramuscular injections, adverse device effects, subcutaneous lipodystrophy and barb phenomenon. 33.33% reported less hypoglycemic events, bleeding, bruising and needle bending with the shorter needle, the others showed no difference. All of the studies considered the shorter needle was undifferentiated with the longer in the needle break, hyperglycemia and lipohypertrophy. 6.25% have pointed out that the shorter needle was better than the longer in leakage, while 81.25% showed no difference in the length. Thirdly, in terms of subjective feelings, for convenience and acceptance, all studies agreed that shorter needle was superior to the longer. For fear and pain, half of studies suggested that shorter needle was superior to the longer one; the other half thought that there was no difference. In all the studies, 69.23% suggested patients prefer the shorter, 23.08% suggested the patients not prefer a particular needle length. **CONCLUSIONS:** Overall, the effectiveness of insulin pens with longer and shorter needle are comparable in treating diabetes, but the shorter needle is little better in parts of the safety indexes. As for patients' subjective feeling, our findings show that patients are generally willing to accept shorter needle.

#### PDB26

##### ECONOMIC IMPACT OF COMBINING METFORMIN WITH DIPEPTIDYL PEPTIDASE INHIBITORS IN DIABETIC PATIENTS WITH RENAL FAILURE

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**OBJECTIVES:** To evaluate resource use and health costs due to the combination of metformin and dipeptidyl peptidase-4 (DPP-4) inhibitors in patients with diabetes and renal failure (RF) in routine clinical practice. **METHODS:** An observational, retrospective study was performed. Patients aged ≥ 30 years treated with metformin who initiated a second oral antidiabetic treatment in 2008–2009 were included. Two groups of patients were analysed: a) metformin + DPP-4 inhibitors and b) other oral antidiabetics. The main measures were: compliance, persistence, metabolic control (glycosylated haemoglobin <7%) and complications (hypoglycemia, cardiovascular events) and total costs. Patients were followed up for two years. **RESULTS:** We included 395 patients, mean age 70.2 years, 56.5% male: 135 patients received metformin + DPP-4 inhibitors and 260 patients received metformin + other oral antidiabetics. Patients receiving DPP-4 inhibitors showed better compliance (66.0% vs. 60.1%), persistence (57.6% vs. 50.0%) and metabolic control (63.9% vs. 57.3%), respectively, compared with those receiving other oral antidiabetics (p<0.05), and also had a lower rate of hypoglycemia (20.0% vs. 47.7%) and lower total costs (€ 2,486 vs. € 3,002), p = 0.001. **CONCLUSIONS:** Despite the limitations of the study, patients with renal failure treated with DPP-4 inhibitors had better metabolic control, lower rates of hypoglycaemia, and lower health costs for the Spanish national health system.

#### PDB27

##### USES OF ELECTRONIC PATIENT INFORMATION SYSTEMS AND NATIONAL REGISTERS – IMPLEMENTATION OF THE CLINICAL PRACTICE GUIDELINE AND EVALUATION OF COSTS AND USE OF RESOURCES IN PATIENTS WITH INCIDENT TYPE 2 DIABETES IN FINLAND

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**OBJECTIVES:** Effective management of diabetes is the cornerstone for prevention of diabetic complications. However, how well the Finnish Current Care guideline for diabetes is implemented in practice is unknown. Combining local and nationwide patient registers provide a valuable resource for evaluating risks, benefits and costs. The purpose of this study was to identify how the Finnish electronic patient information systems and national registers can be used to explore the treatment for patients with incident type 2 diabetes. **METHODS:** Selected primary and specialty care organizations representing different geographical areas and patient information system providers were invited to participate in the study. Study permits were obtained from several local and nationwide register holders. The study protocol was reviewed by the Ethical Review Board of Hospital District of Helsinki and Uusimaa. **RESULTS:** Register linkage is accomplished using unique personal identification numbers. We collect nationwide data on prescriptions, hospital and primary care, reimbursed dental care, and the causes of death. Cost data are based on hospital benchmarking database, sickness allowances and rehabilitations. We use local registers as a source of information on diagnoses, medical procedures, prescriptions and contact types. High quality laboratory data are also included from several local providers. **CONCLUSIONS:** Register linkages enable longitudinal follow-up of patients for research purposes in Finland. In our study a unique combined register database of diabetic patient cohort is created that improves the evaluation of prognosis and care of diabetic patients. This is a promising and versatile source for research in pharmacoepidemiology.

#### PDB28

##### EPIDEMIOLOGY AND UNMET MEDICAL NEED IN DIABETES MELLITUS TYPE 2 IN GERMANY –RESULTS OF A LITERATURE SEARCH

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**OBJECTIVES:** Diabetes mellitus Typ2 (T2DM) is a metabolic disease characterized by hyperglycemia with a high risk-potential of microvascular and macrovascular complications. In addition to glycemic control important therapy targets are the prevention of hypoglycemia and weight gain as well as blood pressure control due to national guidelines (German Medical Association 2013). To describe the current state of T2DM epidemiology and therapeutic needs in Germany which is mandatory when submitting AMNOG dossiers. **METHODS:** To describe epidemiology of diabetes a targeted literature research was conducted in PubMed in 2014 using the search terms (epidemiology OR incidence OR prevalence). To identify relevant comorbidity information the following terms were used (metabolic syndrome OR glycemic control OR hypoglycemia OR obesity OR blood pressure) and combined with AND diabetes AND Germany. PubMed research was supplemented by additional searches in guidelines in German/English. **RESULTS:** The screening of the epidemiologic results identified nine relevant publications: two specified a T2DM-prevalence of 15.3% and 14.7% (Wittchen et al 2007, Huppertz et al 2009) and two studies estimated a T2DM incidence of 15.8 per 1000 patient years (KORA, MONICA). Treatment prevalence increased from 5.9% in 1998 to 8.9% in 2007 related to the total population (Hauner 2013). Arterial hypertension was the most frequent comorbidity (83%) of T2DM (Hagen et al. 2010). In 2010, a disease management program in North Rhine showed that only 15% of participants with T2DM achieved a BMI <25 (Hagen et al. 2010). Long-term trials investigating the efficacy of antidiabetics on the prevention of macrovascular complications are limited (Drug Commission of German Medical Association 2009; Matthaei et al. 2009). **CONCLUSIONS:** While treatment prevalence is increasing and glycemic control seems to be sufficiently achieved a substantial unmet medical need is identified for antidiabetics with a significant effect on weight reduction and blood pressure control in patients with T2DM in Germany.

#### PDB29

##### PROGRESSION OF PHYSIOLOGICAL PARAMETERS OVER TIME IN TYPE 1 DIABETES MELLITUS PATIENTS IN FRANCE

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**OBJECTIVES:** The objective of this study was to understand the progression over time of physiological parameters, including HbA1c, body mass index (BMI), systolic blood pressure (SBP), total cholesterol, LDL-cholesterol, HDL-cholesterol and triglycerides, in type 1 diabetes mellitus (T1DM) patients to inform disease modeling. **METHODS:** This was a cross-sectional analysis of T1DM patients based on the IMS LifeLink Diabetes Cohort in France, which prospectively collects clinical, biological and treatment information from general practitioners. Patient age, gender, year of diagnosis, BMI, HbA1c, cardiovascular risk factors, renal function and lab test results were collected at baseline and subsequent visits. Data were analyzed using R Studio. T1DM patients who visited their general physician between May 2011 and May 2014 and have received at least one insulin prescription were included in the analysis. **RESULTS:** A cohort of 605 T1DM patients was included in this analysis. Forty-three percent of patients were male. Average patient age at first visit was 58 years of age. Mean HbA1c was 7.8%, mean SBP was 132 mmHg, and mean BMI was 27.6 kg/m<sup>2</sup>. Linear regression showed that BMI increased by 0.092 kg/m<sup>2</sup> (p<0.001) for each additional year of age. SBP was projected to increase by 0.248 mmHg (p<0.001) per additional year of age. LDL-cholesterol decreased by

0.624 mg/dL for each additional ( $p=0.017$ ) year of age and triglycerides increased by 1.417 mg/dL for each additional ( $p=0.041$ ) year of age. Changes in HbA1c, total cholesterol and HDL-cholesterol over time were not significantly correlated with patient age or time since diagnosis. Therefore, health economic modelers may assume that these parameters remain stable over time. Sensitivity analyses were performed to address the potential mislabeling of T2DM as T1DM patients. **CONCLUSIONS:** These results provide relevant inputs for the progression of physiological parameters to model the economic and clinical impacts of T1DM therapies over time.

#### PDB30

##### TREND IN PREVALENCE AND DISTRIBUTION OF DIABETES MELLITUS TYPE I AND TYPE II IN THE NETHERLANDS

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**OBJECTIVES:** To quantify the trend in prevalence and distribution of diabetes mellitus (DM) type I (T1DM) and type II (T2DM) in the Netherlands. **METHODS:** Using the General Practitioner Database and the Out-patient Pharmacy Database of the PHARMO Database Network, the trend in prevalence of DM and distribution of T1DM and T2DM from 2005 to 2012 was assessed. Per year, patients with  $\geq 2$  anti-diabetic drug dispensings within 6 months were selected as DM patient. Patient numbers were extrapolated to the Netherlands to determine prevalence of DM. For all patients, diabetes treatment at September 30 of that year was assessed. For patients with a GP recorded diagnosis for T1DM or T2DM, distribution of T1DM/T2DM was stratified by treatment. This distribution of DM type by treatment was applied to the treatment of patients with no GP recorded DM type to assess the distribution of T1DM/T2DM. **RESULTS:** The prevalence of DM in the Netherlands increased from 38 per 1000 males and 40 per 1000 females in 2005 to 54 per 1000 males and 52 per 1000 females in 2012. The distribution of T1DM versus T2DM among patients with DM changed from 15% versus 85% in 2005 to 8% versus 92% in 2012. Among patients with T1DM mean ( $\pm$ SD) age decreased from 48 ( $\pm 22$ ) years in 2005 to 44 ( $\pm 22$ ) years in 2012. Among patients with T2DM mean age increased from 63 ( $\pm 12$ ) years in 2005 to 67 ( $\pm 12$ ) years in 2012. **CONCLUSIONS:** This study describes the epidemiology of DM in the Netherlands over 2005–2012. Prevalence of DM increased and relatively more patients were diagnosed with T2DM. These changes can be explained by the ageing Dutch population, better survival, more obesity and early detection of T2DM. Furthermore, introduction of the T2DM care program in 2005 probably has led to a better registration of T2DM patients.

#### PDB31

##### FACTORS ASSOCIATED WITH HOSPITALIZATION OF TYPE 2 DIABETIC PATIENTS WITH HYPOGLYCEMIC EPISODES ASSISTED AT EMERGENCY DEPARTMENTS

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#### PDB32

##### THE IMPACT OF TREATMENT OF THYROID DISEASE IN PREGNANT WOMEN TO THE OUTCOME OF GIVING BIRTH

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**OBJECTIVES:** The most common endocrine clinical symptom is thyroid disease which has impact to pregnant women and fetus. Leading international references about its treatments are well known, there is no relevant experiences in the Hungarian context. Aim of this study is to inspect the thyroid disease and impact of its treatment to outcome of pregnancy. **METHODS:** Survey was carried out at Markusovszky Hospital in Vas County, Hungary. Retrospective study made by data analysis of pregnant patient with thyroid disease, including hormone parameters,

medications and obstetric medical history. Set-up was non-random, convenience sampling with 40 women's data with mean age  $33.7 \pm 3.6$ , between August 2013 – February 2014. Friedmann ANOVA and t-test was applied for analysis with software Statistics for Windows. **RESULTS:** Progresses the gestation period significant reduction of TSH values was observed in hypothyroid patients ( $p=0.0075$ ). Comparing successive TSH values of the individual patients showed the same significant difference. Significant negative correlation was founded between TSH value and thyroxine dose in group of hypothyroid patients ( $r=-0.35$ ;  $p<0.05$ ). Premature birth and other obstetric complications occurred more frequently in the thyrotoxic group, especially among older women giving birth. **CONCLUSIONS:** In case of hypothyroid pregnant with increasing dose of thyroxine the TSH levels are well balanced, and obstetric complications did not occur, while in hyperthyroid patients can be reported obstetric complications in addition to proper care.

#### DIABETES/ENDOCRINE DISORDERS – Cost Studies

#### PDB33

##### BUDGET IMPACT ANALYSIS OF ADDING DAPAGLIFOZIN TO THE THERAPY OF DIABETES MELLITUS TYPE 2 IN BULGARIA

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**OBJECTIVES:** Dapagliflozin is a highly potent, selective and reversible inhibitor of sodium-glucose co-transporter 2 (SGLT2) and is approved for the treatment of T2DM in adults. Diabetes type 2 is one of the most prevalent chronic diseases that can lead to serious complications and disability. The largest costs are those associated with hospitalizations due to the complications, the prevention of which requires a good glycemic control. The objective of the study is to estimate the budget impact of adding dapagliflozin to the therapy of type 2 diabetes in Bulgaria. **METHODS:** The budget impact model was used from the payer perspective for population 7 284 552 people, and out of them 450000 are type 2 diabetics. The retail pharmacy prices were used from the Positive Drug List. Official IMS data for antidiabetic medicines were incorporated in the model. Net budget impact is presented as costs per-member per-month (PMPM) and costs per-patient per-year (PPPY). **RESULTS:** An increase in the estimated net budget impact from 70 592 € first year to 1 290 716 € for the fifth year was observed after adding dapagliflozin to T2DM therapy, with a cumulative net budget impact of 3 258 047 €. PMPM and PPPY costs show minimal growth with respective cumulative values of 0.06 € and of 65.63 €. The cost for dapagliflozin therapy is comparable to that of DPP-4 inhibitors and is lower than the cost of treatment with a GLP-1. **CONCLUSIONS:** The results show that adding dapagliflozin to standard therapy will lead to minimal increase in the diabetes type 2 budget in Bulgaria. This increase is considered acceptable in terms of better glycemic control with safe and effective therapy for diabetes type 2.

#### PDB34

##### ASSESSMENT OF THE ECONOMIC VALUE OF DPP-4 INHIBITOR ALOGLIPTIN COMPARED WITH SITAGLIPTIN, SAXAGLIPTIN, AND LINAGLIPTIN

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**OBJECTIVES:** Objective of this study is to provide additional evidence for decision making to payers assessing health care resource utilization, economic impact, and cost-effectiveness of DPP-4 inhibitor alogliptin compared with sitagliptin, saxagliptin and linagliptin, for the treatment of type-2 diabetes mellitus (T2DM). **METHODS:** 29 comparable, randomized clinical trials were selected out of a panel of 58 studies. 6 different clinical endpoints (efficacy and safety) were compared across 5 different combinations: DPP-4 Monotherapy, +metformin (MET), +sulfonylurea (SU), +thiazolidinedione (TZD), +insulin (INS). For each endpoint and combination, alogliptin clinical endpoints were compared with respective average endpoints of other DPP-4s. Differentials were calculated after adjustment for baseline characteristics. Each endpoint was associated with the impact on patient outcomes and related health care costs (T2DM-related complications, treatment escalation, costs associated with adverse events: hypoglycemia, cardiovascular mortality, hospitalization due to heart failure, lipids profile) obtained from published data. Economic value saving of alogliptin was calculated and compared to the other DPP-4s. **RESULTS:** The proportion of patients at target (HbA1c<7%) as well as the reduced need for treatment escalation with alogliptin could generate annual savings for a health care system of €69.62 and €22.97 per patient-year, respectively. Improved lipids profile and proven CV safety of alogliptin can generate savings of €40.86 and €21.47 per patient-year, respectively. Impact of lower hypoglycemia and increased adherence with fixed dose combinations with TZD may generate additional savings (€1.53 and €1.60/ patient-year, respectively). **CONCLUSIONS:** This study suggests that alogliptin could generate significant savings for a Healthcare System, even at price parity with other DPP-4s, thanks to its efficacy and safety profile, particularly in the widely used DPP-4+MET combination. Total savings of up to €158 per patient-year compare favorably with an overall cost of treatment with a DPP-4i ranging from €350 to €481 per patient-year.

#### PDB35

##### COST-EFFECTIVENESS ANALYSIS OF AUTOCODED AND MANUALLY CODED BLOOD GLUCOSE METERS IN DIABETES TREATMENT

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**OBJECTIVES:** To conduct a cost-effectiveness assessment of glucose meters (manually coded and autocoded) in diabetes treatment in the Russian Federation. **METHODS:** Clinical effectiveness assessment was based on the results of modeling of the treatment of patients with diabetes that use manually coded and autocoded blood glucose meters. Cost analysis included assessment of direct and indirect costs that can be